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10/588,924

03/26/2007

Olaf Gebauer

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BAYER CROPSCIENCE LP

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EXAMINER

MOORE, SUSANNA

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

02/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/588,924 | GEBAUER ET AL. | |
| | Examiner | Art Unit | |
| | SUSANNA MOORE | 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/11/07</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

There are 9 claims pending and 9 under consideration. Claims 11-19 are drawn to imidazolo[1,2-a]pyrimidine compounds, simple compositions, a process of making simple compositions and a method of treating unwanted microorganisms. This is a first action on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/11/2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. There are several references missing from the file. Please resubmit the reference prior to a final office action for consideration.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Substituted Imidazolo[1,2-a]pyrimidines to Control Microorganisms.

Claim Objections

Claims 11 and 12 are objected to because of the following informalities: the term "radicals" should be replaced with "radical" in claim 11, page 3, line 18, claim 12, page 5, lines 15, 22 and 23. Appropriate correction is required.

Claims 12-19 are objected to because of the following informalities: the term "Claim" should be replaced with "claim" in claims 12-19. Claim 15 has 3 occurrences. Appropriate correction is required.

Claim 19 is objected to because of the following informalities: after the period there is "--", which should be removed. Appropriate correction is required.

Claim 12 is objected to because of the following informalities: the term "halolkenyl/oxy" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "1 to 13 carbon atoms" in the definition of R¹ and R². There is insufficient antecedent basis for this limitation in the claim. See page 5, lines 3 and 7.

Claims 12 and 13 recite the limitation "H" in the definition of X. There is insufficient antecedent basis for this limitation in the claim.

Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Such a utility cannot be deemed enabled. Pursuant to *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444. The analysis is as follows:

(A) Breadth of claims.

(a) Scope of the compounds. The instant claims encompass millions of compounds with an imidazolo[1,2-a]pyrimidine scaffold with a variety of substituents at five positions.

(b) Scope of the diseases covered. The instant claims are drawn to a method of controlling all unwanted microorganisms. The definition of a microorganism is a microbe, which is an organism that is microscopic (too small to be visible to the naked eye). Microorganisms are often described as single-celled, or unicellular organisms; however, some unicellular protists are visible to the naked eye, and some multicellular species are microscopic. As recited, the scope of the claim can include, but is not limited to:

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Bacteria:

Aerobic gram positive: enterococcus faecalis, enterococcus faecium, staphylococcus aureus, staphylococcus epidermidis, staphylococcus saprophyticus, staphylococcus pneumoniae, staphylococcus pyogenes, staphylococcus haemolyticus and staphylococcus hominis.

Aerobic gram negative: campylobacter jejuni, citrobacter diversus, citrobacter freundii, enterobacter cloacae, escherichia coli, haemophilus influenzae, haemophilus parainfluenzae, klebsiella pneumoniae, moraxella catarrhalis, morganella morganii, neisseria gonorrhoeae, proteus mirabilis, proteus vulgaris, providencia rettgeri, providencia stuartii, pseudomonas aeruginosa, stenotrophomonas maltophilia, salmonella typhi, serratia marcescens, shigella boydii, shigella dysenteriae, shigella flexneri, shigella sonnei, acinetobacter iwoffii, aeromonas hydrophila, edwardsiella tarda, enterobacter aerogenes, klebsiella oxytoca, legionella pneumophila, pasteurilla multocida, salmonella enteritidis, vibrio cholerae, vibrio parahaemolyticus, vibrio vulnificus, yersinia enterocolitica and H. pylori.

Viroids: potato spindle tuber viroid, hop stunt viroid, coconut cadang-cadang viroid, apple scar skin viroid, coleus blumei viroid 1, avocado sunblotch viroid, and peach latent mosaic viroid;

Viruses: hepatitis A, B, C, D and E, influenza virus, herpes simplex virus, molluscum contagiosum, and HIV;

Protozoa: cryptosporidium, giardia lamblia, plasmodium and trypanosoma cruzi; Fungi: pneumocystis jiroveci, tinea, chytrids, and candida.

Viroids: potato spindle tuber viroid, hop stunt viroid, coconut cadang-cadang viroid, apple scar skin viroid, coleus blumei viroid 1, avocado sunblotch viroid, and peach latent mosaic viroid.

This is just a small portion of the scope for infections by organisms. There are many more.

(B) The nature of the invention and predictability in the art: The invention is directed toward controlling all unwanted microorganisms and therefore is physiological in nature. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(C) Direction or Guidance: That provided is very limited. The dosage range information, found on pages 26 of the Specification gives 10-1000 g/ha for parts and plants and 0.0001 and 50 g for seed treatments, 0.01-10 g/h for seed treatments and 0.1-5000 g/h for soil treatment, which is very broad. Moreover, this is generic, the same for the many unwanted microorganisms covered by the specification. Thus, there is no specific direction or guidance regarding a regimen or dosage effective specifically for all unwanted microorganism covered by the scope of the claim.

(D) State of the Prior Art: These compounds are substituted imidazolo[1,2-a]pyrimidines. So far as the examiner is aware, no substituted imidazolo[1,2-a]pyrimidines of any kind have been used for inhibiting or treating all unwanted microorganisms.

(E) Working Examples: The invention is drawn to a method of controlling all unwanted microorganism. There are only three tests found in the Specification drawn to the utility of controlling fungi. On pages 64-70 of the Specification several tests are presented, an *Alternaria*

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mali, Ustilago avenae, and Botrytis cinerea test, which only provide data to support the utility to support the method of controlling fungi growth. No data is present for controlling all unwanted microorganisms.

(F) Skill of those in the art: Microorganisms are all different and challenging to treat and generally cannot be treated by any one compound. For instance, antibiotics are usually effect against either gram positive or gram negative bacteria. There are very few that have been able to treat both types of bacteria. These "super drugs" are usually kept for resistant strains because they are so valuable and hard to come by. Furthermore, HIV can only be treated with an anti-viral, a property these compounds are not disclosed to have.

(G) The quantity of experimentation needed: Owing especially to factors A, C, E and F, the amount of experimentation is expected to be high. MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

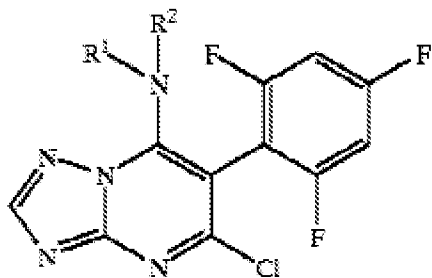
Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pees et. al. (US 6117876) in view of Krummel et. al. (US 5808066).

The instant Application claims compounds of formula (I), imidazo[1,2-a]pyrimidines, wherein X= Cl, R⁴= hydrogen, R³= 2,4,6-trifluorophenyl, R¹= hydrogen and R²= CH₂Si(CH₃)₃, simple compositions, process of making the simple compositions, process of making said compounds, and a method of use as a fungicide.

Pee et. al. teaches compounds of formula (I) as antifungals, wherein X= Cl, R⁴= hydrogen, R³= 2,4,6-trifluorophenyl, R¹= hydrogen and R²= CH₂Si(CH₃)₃, see column 13,

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compound 35. Also note compound 40 is embraced by claim 1, see below. The antifungal compositions are taught in columns 9-10, with a surfactant, see column 10, line 36.



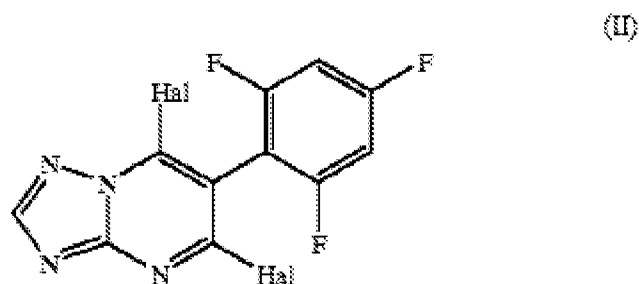
| | | | |
|----|----------------------|----------------------|---------|
| 35 | trimethylsilylmethyl | H | 148-150 |
| 40 | trimethylsilylmethyl | 2,2,2-trifluoroethyl | 85 |

The process of making said compounds is found in column 6, lines 60-62, see below.

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The present invention further provides a process for the preparation of a compound of formula I as defined above which comprises

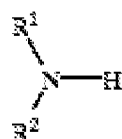
treating a compound of the general formula II



in which

Hal is as defined for formula I;

with an amine of the general formula III



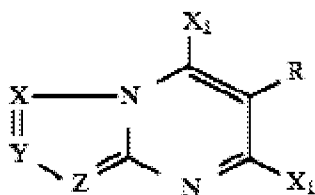
in which

R¹ and R² are as defined for formula I,

to produce a compound of formula I

Pees does not teach the imidazo[1,2-a]pyrimidine bicyclic core.

Krummel et. al. teaches the equivalency of the imidazo[1,2-a]pyrimidine and the [1,2,4]triazolo[1,5-a]pyrimidine core as an antifungal, see column 1, lines 40-45, formula (I) and column 2, lines 4-6.



X is CR₁ or N;

Y is CR₂ or N;

Z is CR₃ or N;

Thus, the imidazo[1,2-a]pyrimidine and the [1,2,4]triazolo[1,5-a]pyrimidine core are alternatively useable as antifungals. The instant Application is rendered obvious by Pees et. al. in view of Krummel et. al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624